

**BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA**

In the Matter of the Accusation Against:

**PACIFIC HEALTHCARE INC. DBA B &
B PHARMACY, JANE E. HYUN, HYUN
JOON RO, OWNERS
10244 Rosecrans Ave.
Bellflower, CA 90706**

**Original Permit No. PHY 50799
Sterile Compounding Permit No. LSC 99714**

and

**SUZY MICHEL MORKOS
6222 Forester Dr.
Huntington Beach, CA 92648**

Pharmacist License No. RPH 47817

Respondents.

Case No. 6022

OAH No. 2017090416

**STIPULATED SETTLEMENT AND
DISCIPLINARY ORDER AS TO
RESPONDENT SUZY MICHEL
MORKOS, ONLY**

DECISION AND ORDER

The attached Stipulated Settlement and Disciplinary Order is hereby adopted by the Board of Pharmacy, Department of Consumer Affairs, as its Decision in this matter.

This Decision shall become effective at 5:00 p.m. on April 26, 2018.

It is so ORDERED on March 27, 2018.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA



By _____

Amy Gutierrez, Pharm.D.
Board President

1 XAVIER BECERRA
Attorney General of California
2 THOMAS L. RINALDI
Supervising Deputy Attorney General
3 EMILY Y. WADA
Deputy Attorney General
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Attorneys for Complainant

7
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9 **DEPARTMENT OF CONSUMER AFFAIRS**
STATE OF CALIFORNIA

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16 **Sterile Compounding Permit No. LSC**
17 **99714,**

18 **and**

19 **SUZY MICHEL MORKOS**
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20 **Huntington Beach, CA 92648**

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STIPULATED SETTLEMENT AND
DISCIPLINARY ORDER AS TO
RESPONDENT SUZY MICHEL
MORKOS, ONLY

23 IT IS HEREBY STIPULATED AND AGREED by and between the parties to the above-
24 entitled proceedings that the following matters are true:

25 **PARTIES**

26 1. Virginia Herold ("Complainant") is the Executive Officer of the Board of Pharmacy
27 ("Board"). She brought this action solely in her official capacity and is represented in this matter
28

1 by Xavier Becerra, Attorney General of the State of California, by Emily Y. Wada, Deputy
2 Attorney General.

3 2. Respondent Suzy Michel Morkos ("Respondent") is represented in this proceeding by
4 attorney Tony J. Park, Esq., whose address is: California Pharmacy Lawyers, 49 Discovery, Suite
5 240, Irvine, CA 92618-6713, Telephone (949) 336-7854.

6 3. On or about March 8, 1995, the Board of Pharmacy issued Pharmacist License
7 Number RPH 47817 to Respondent. The Pharmacist License was in full force and effect at all
8 times relevant to the charges brought herein and will expire on July 31, 2018, unless renewed.

9 JURISDICTION

10 4. Accusation No. 6022 was filed before the Board, and is currently pending against
11 Respondent. The Accusation and all other statutorily required documents were properly served
12 on Respondent on July 12, 2018. Respondent timely filed her Notice of Defense contesting the
13 Accusation.

14 5. A copy of Accusation No. 6022 is attached as Exhibit A and incorporated herein by
15 reference.

16 ADVISEMENT AND WAIVERS

17 6. Respondent has carefully read, fully discussed with counsel, and understands the
18 charges and allegations in Accusation No. 6022. Respondent has also carefully read, fully
19 discussed with counsel, and understands the effects of this Stipulated Settlement and Disciplinary
20 Order.

21 7. Respondent is fully aware of her legal rights in this matter, including the right to a
22 hearing on the charges and allegations in the Accusation; the right to confront and cross-examine
23 the witnesses against them; the right to present evidence and to testify on her own behalf; the
24 right to the issuance of subpoenas to compel the attendance of witnesses and the production of
25 documents; the right to reconsideration and court review of an adverse decision; and all other
26 rights accorded by the California Administrative Procedure Act and other applicable laws.

27 8. Respondent voluntarily, knowingly, and intelligently waives and gives up each and
28 every right set forth above.

1 CULPABILITY

2 9. Respondent admits the truth of each and every charge and allegation in Accusation
3 No. 6022.

4 10. Respondent agrees that her Pharmacist License is subject to discipline and she agrees
5 to be bound by the Board's probationary terms as set forth in the Disciplinary Order below.

6 CONTINGENCY

7 11. This stipulation shall be subject to approval by the Board of Pharmacy. Respondent
8 understands and agrees that counsel for Complainant and the staff of the Board of Pharmacy may
9 communicate directly with the Board regarding this stipulation and settlement, without notice to
10 or participation by Respondent or her counsel. By signing the stipulation, Respondent
11 understands and agrees that they may not withdraw her agreement or seek to rescind the
12 stipulation prior to the time the Board considers and acts upon it. If the Board fails to adopt this
13 stipulation as its Decision and Order, the Stipulated Settlement and Disciplinary Order shall be of
14 no force or effect, except for this paragraph, it shall be inadmissible in any legal action between
15 the parties, and the Board shall not be disqualified from further action by having considered this
16 matter.

17 12. The parties understand and agree that Portable Document Format (PDF) and facsimile
18 copies of this Stipulated Settlement and Disciplinary Order, including PDF and facsimile
19 signatures thereto, shall have the same force and effect as the originals.

20 13. This Stipulated Settlement and Disciplinary Order is intended by the parties to be an
21 integrated writing representing the complete, final, and exclusive embodiment of their agreement.
22 It supersedes any and all prior or contemporaneous agreements, understandings, discussions,
23 negotiations, and commitments (written or oral). This Stipulated Settlement and Disciplinary
24 Order may not be altered, amended, modified, supplemented, or otherwise changed except by a
25 writing executed by an authorized representative of each of the parties.

26 14. In consideration of the foregoing admissions and stipulations, the parties agree that
27 the Board may, without further notice or formal proceeding, issue and enter the following
28 Disciplinary Order:

1 **DISCIPLINARY ORDER**

2 IT IS HEREBY ORDERED that Pharmacist License Number RPH 47817 issued to
3 Respondent is revoked. However, the revocation is stayed and Respondent is placed on probation
4 for three (3) years on the following terms and conditions.

5 **1. Obey All Laws**

6 Respondent shall obey all state and federal laws and regulations.

7 Respondent shall report any of the following occurrences to the board, in writing, within
8 seventy-two (72) hours of such occurrence:

- 9 • an arrest or issuance of a criminal complaint for violation of any provision of the
10 Pharmacy Law, state and federal food and drug laws, or state and federal controlled
11 substances laws
12 • a plea of guilty or nolo contendere in any state or federal criminal proceeding to any
13 criminal complaint, information or indictment
14 • a conviction of any crime
15 • discipline, citation, or other administrative action filed by any state or federal agency
16 which involves respondent's pharmacist license or which is related to the practice of
17 pharmacy or the manufacturing, obtaining, handling, distributing, billing, or charging
18 for any drug, device or controlled substance.

19 Failure to timely report such occurrence shall be considered a violation of probation.

20 **2. Report to the Board**

21 Respondent shall report to the board quarterly, on a schedule as directed by the board or its
22 designee. The report shall be made either in person or in writing, as directed. Among other
23 requirements, respondent shall state in each report under penalty of perjury whether there has
24 been compliance with all the terms and conditions of probation. Failure to submit timely reports
25 in a form as directed shall be considered a violation of probation. Any period(s) of delinquency
26 in submission of reports as directed may be added to the total period of probation. Moreover, if
27 the final probation report is not made as directed, probation shall be automatically extended until
28 such time as the final report is made and accepted by the board.

1 **3. Interview with the Board**

2 Upon receipt of reasonable prior notice, respondent shall appear in person for interviews
3 with the board or its designee, at such intervals and locations as are determined by the board or its
4 designee. Failure to appear for any scheduled interview without prior notification to board staff,
5 or failure to appear for two (2) or more scheduled interviews with the board or its designee during
6 the period of probation, shall be considered a violation of probation.

7 **4. Cooperate with Board Staff**

8 Respondent shall cooperate with the board's inspection program and with the board's
9 monitoring and investigation of respondent's compliance with the terms and conditions of their
10 probation. Failure to cooperate shall be considered a violation of probation.

11 **5. Continuing Education**

12 Respondent shall provide evidence of efforts to maintain skill and knowledge as a
13 pharmacist as directed by the board or its designee.

14 **6. Notice to Employers**

15 During the period of probation, respondent shall notify all present and prospective
16 employers of the decision in case number 6022 and the terms, conditions and restrictions imposed
17 on respondent by the decision, as follows:

18 Within thirty (30) days of the effective date of this decision, and within fifteen (15) days of
19 respondent undertaking any new employment, respondent shall cause their direct supervisor,
20 pharmacist-in-charge (including each new pharmacist-in-charge employed during respondent's
21 tenure of employment) and owner to report to the board in writing acknowledging that the listed
22 individual(s) has/have read the decision in case number 6022, and terms and conditions imposed
23 thereby. It shall be respondent's responsibility to ensure that their employer(s) and/or
24 supervisor(s) submit timely acknowledgment(s) to the board.

25 If respondent works for or is employed by or through a pharmacy employment service,
26 respondent must notify their direct supervisor, pharmacist-in-charge, and owner at every entity
27 licensed by the board of the terms and conditions of the decision in case number 6022 in advance
28

1 of the respondent commencing work at each licensed entity. A record of this notification must be
2 provided to the board upon request.

3 Furthermore, within thirty (30) days of the effective date of this decision, and within fifteen
4 (15) days of respondent undertaking any new employment by or through a pharmacy employment
5 service, respondent shall cause their direct supervisor with the pharmacy employment service to
6 report to the board in writing acknowledging that they has read the decision in case number 6022
7 and the terms and conditions imposed thereby. It shall be respondent's responsibility to ensure
8 that their employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the board.

9 Failure to timely notify present or prospective employer(s) or to cause that/those
10 employer(s) to submit timely acknowledgments to the board shall be considered a violation of
11 probation.

12 "Employment" within the meaning of this provision shall include any full-time,
13 part-time, temporary, relief or pharmacy management service as a pharmacist or any
14 position for which a pharmacist license is a requirement or criterion for employment,
15 whether the respondent is an employee, independent contractor or volunteer.

16 **7. No Supervision of Interns, Serving as Pharmacist-in-Charge (PIC), Serving as**
17 **Designated Representative-in-Charge, or Serving as a Consultant**

18 During the period of probation, respondent shall not supervise any intern pharmacist, be the
19 pharmacist-in-charge or designated representative-in-charge of any entity licensed by the board
20 nor serve as a consultant unless otherwise specified in this order. Assumption of any such
21 unauthorized supervision responsibilities shall be considered a violation of probation.

22 **8. Reimbursement of Board Costs**

23 As a condition precedent to successful completion of probation, respondent shall pay to the
24 board its costs of investigation and prosecution in the amount of \$500.00. Respondent shall make
25 said payments in accordance with a schedule set by the board or its designee.

26 There shall be no deviation from this schedule absent prior written approval by the board or
27 its designee. Failure to pay costs by the deadline(s) as directed shall be considered a violation of
28 probation.

1 The filing of bankruptcy by respondent shall not relieve respondent of their responsibility to
2 reimburse the board its costs of investigation and prosecution.

3 **9. Probation Monitoring Costs**

4 Respondent shall pay any costs associated with probation monitoring as determined by the
5 board each and every year of probation. Such costs shall be payable to the board on a schedule as
6 directed by the board or its designee. Failure to pay such costs by the deadline(s) as directed shall
7 be considered a violation of probation.

8 **10. Status of License**

9 Respondent shall, at all times while on probation, maintain an active, current license with
10 the board, including any period during which suspension or probation is tolled. Failure to
11 maintain an active, current license shall be considered a violation of probation.

12 If respondent's license expires or is cancelled by operation of law or otherwise at any time
13 during the period of probation, including any extensions thereof due to tolling or otherwise, upon
14 renewal or reapplication respondent's license shall be subject to all terms and conditions of this
15 probation not previously satisfied.

16 **11. License Surrender While on Probation/Suspension**

17 Following the effective date of this decision, should respondent cease practice due to
18 retirement or health, or be otherwise unable to satisfy the terms and conditions of probation,
19 respondent may tender their license to the board for surrender. The board or its designee shall
20 have the discretion whether to grant the request for surrender or take any other action it deems
21 appropriate and reasonable. Upon formal acceptance of the surrender of the license, respondent
22 will no longer be subject to the terms and conditions of probation. This surrender constitutes a
23 record of discipline and shall become a part of the respondent's license history with the board.

24 Upon acceptance of the surrender, respondent shall relinquish their pocket and wall license
25 to the board within ten (10) days of notification by the board that the surrender is accepted.
26 Respondent may not reapply for any license from the board for three (3) years from the effective
27 date of the surrender. Respondent shall meet all requirements applicable to the license sought as
28

1 of the date the application for that license is submitted to the board, including any outstanding
2 costs.

3 **12. Notification of a Change in Name, Residence Address, Mailing Address or**
4 **Employment**

5 Respondent shall notify the board in writing within ten (10) days of any change of
6 employment. Said notification shall include the reasons for leaving, the address of the new
7 employer, the name of the supervisor and owner, and the work schedule if known. Respondent
8 shall further notify the board in writing within ten (10) days of a change in name, residence
9 address, mailing address, or phone number.

10 Failure to timely notify the board of any change in employer(s), name(s), address(es), or
11 phone number(s) shall be considered a violation of probation.

12 **13. Tolling of Probation**

13 Except during periods of suspension, respondent shall, at all times while on probation, be
14 employed as a pharmacist in California for a minimum of thirty (30) hours per calendar month.
15 Any month during which this minimum is not met shall toll the period of probation, i.e., the
16 period of probation shall be extended by one month for each month during which this minimum is
17 not met. During any such period of tolling of probation, respondent must nonetheless comply
18 with all terms and conditions of probation.

19 Should respondent, regardless of residency, for any reason (including vacation) cease
20 practicing as a pharmacist for a minimum of thirty (30) hours per calendar month in California,
21 respondent must notify the board in writing within ten (10) days of the cessation of practice, and
22 must further notify the board in writing within ten (10) days of the resumption of practice. Any
23 failure to provide such notification(s) shall be considered a violation of probation.

24 It is a violation of probation for respondent's probation to remain tolled pursuant to the
25 provisions of this condition for a total period, counting consecutive and non-consecutive months,
26 exceeding thirty-six (36) months.

27 "Cessation of practice" means any calendar month during which respondent is not
28 practicing as a pharmacist for at least thirty (30) hours, as defined by Business and Professions

1 Code section 4000 et seq . "Resumption of practice" means any calendar month during which
2 respondent is practicing as a pharmacist for at least thirty (30) hours as a pharmacist as defined by
3 Business and Professions Code section 4000 et seq.

4 **14. Violation of Probation**

5 If a respondent has not complied with any term or condition of probation, the board shall
6 have continuing jurisdiction over respondent, and probation shall automatically be extended, until
7 all terms and conditions have been satisfied or the board has taken other action as deemed
8 appropriate to treat the failure to comply as a violation of probation, to terminate probation, and
9 to impose the penalty that was stayed.

10 If respondent violates probation in any respect, the board, after giving respondent notice
11 and an opportunity to be heard, may revoke probation and carry out the disciplinary order that
12 was stayed. Notice and opportunity to be heard are not required for those provisions stating that a
13 violation thereof may lead to automatic termination of the stay and/or revocation of the license. If
14 a petition to revoke probation or an accusation is filed against respondent during probation, the
15 board shall have continuing jurisdiction and the period of probation shall be automatically
16 extended until the petition to revoke probation or accusation is heard and decided.

17 **15. Completion of Probation**

18 Upon written notice by the board or its designee indicating successful completion of
19 probation, respondent's license will be fully restored.

20 **16. Remedial Education**

21 Within thirty (30) days of the effective date of this decision, respondent shall submit to the
22 board or its designee, for prior approval, an appropriate program of remedial education related to
23 compounding and/or the role of a pharmacist-in-charge. The program of remedial education shall
24 consist of at least six (6) hours, which shall be completed each year that respondent is on
25 probation and at respondent's own expense. All remedial education shall be in addition to, and
26 shall not be credited toward, continuing education (CE) courses used for license renewal
27 purposes.

28 Failure to timely submit or complete the approved remedial education shall be considered a

1 violation of probation. The period of probation will be automatically extended until such
2 remedial education is successfully completed and written proof, in a form acceptable to the board,
3 is provided to the board or its designee.

4 Following the completion of each course, the board or its designee may require the
5 respondent, at their own expense, to take an approved examination to test the respondent's
6 knowledge of the course. If the respondent does not achieve a passing score on the examination,
7 this failure shall be considered a violation of probation. Any such examination failure shall
8 require respondent to take another course approved by the board in the same subject area.

9 **17. No Ownership of Licensed Premises**

10 Respondent shall not own, have any legal or beneficial interest in, or serve as a manager,
11 administrator, member, officer, director, trustee, associate, or partner of any business, firm,
12 partnership, or corporation currently or hereinafter licensed by the board. Respondent shall sell
13 or transfer any legal or beneficial interest in any entity licensed by the board within ninety (90)
14 days following the effective date of this decision and shall immediately thereafter provide written
15 proof thereof to the board. Failure to timely divest any legal or beneficial interest(s) or provide
16 documentation thereof shall be considered a violation of probation.

17 Respondent shall not acquire any new ownership, legal or beneficial interest nor serve as a
18 manager, administrator, member, officer, director, trustee, associate, or partner of any additional
19 business, firm, partnership, or corporation licensed by the board. If respondent currently owns or
20 has any legal or beneficial interest in, or serves as a manager, administrator, member, officer,
21 director, trustee, associate, or partner of any business, firm, partnership, or corporation currently
22 or hereinafter licensed by the board, respondent may continue to serve in such capacity or hold
23 that interest, but only to the extent of that position or interest as of the effective date of this
24 decision. Violation of this restriction shall be considered a violation of probation.

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26 ///


27 ///

28 ///

1 ACCEPTANCE

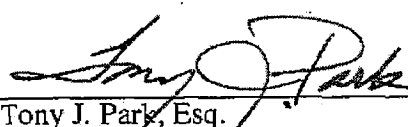
2 I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully
3 discussed it with my attorney, Tony J. Park. I understand the stipulation and the effect it will
4 have on my Original Permit, and Sterile Compounding Permit. I enter into this Stipulated
5 Settlement and Disciplinary Order voluntarily, knowingly, and intelligently, and agree to be
6 bound by the Decision and Order of the Board of Pharmacy.

7
8 DATED: 2/14/18


9 SUZY MICHEL MORKOS
Respondent

10 I have read and fully discussed with Respondent Suzy Michel Morkos the terms and
11 conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order.
12 I approve its form and content.

13
14
15 DATED: 02/14/2018


16 Tony J. Park, Esq.
Attorney for Respondent

17
18 ENDORSEMENT

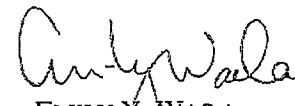
19 The foregoing Stipulated Settlement and Disciplinary Order is hereby respectfully
20 submitted for consideration by the Board of Pharmacy.

21 Dated:

22 February 14, 2018

Respectfully submitted,

23 XAVIER BECERRA
Attorney General of California
24 THOMAS L. RINALDI
Supervising Deputy Attorney General

25 
26 EMILY Y. WADA
27 Deputy Attorney General
Attorneys for Complainant

28 LA2016602903/52802590.docx

Exhibit A

Accusation No. 6022

1 XAVIER BECERRA
Attorney General of California
2 THOMAS L. RINALDI
Supervising Deputy Attorney General
3 EMILY Y. WADA
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Attorneys for Complainant

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15 **SUZY MICHEL MORKOS**
16 6222 Forester Dr.
Huntington Beach, CA 92648
17 Pharmacist License No. RPH 47817

18 Respondents.

Case No. 6022

ACCUSATION

19 Complainant alleges:

20 **PARTIES**

21 1. Virginia Herold ("Complainant") brings this Accusation solely in her official capacity
22 as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs.

23 2. On or about December 22, 2011, the Board of Pharmacy issued Original Permit
24 Number PHY 50799 to Pacific Healthcare Inc., dba B&B Pharmacy, Jane E. Hyun, Hyun Joon Ro
25 ("B&B Pharmacy"). The Original Permit expired on April 15, 2016, and has not been renewed.

26 ///

27 ///

3. On or about January 31, 2012, the Board of Pharmacy issued Sterile Compounding Permit Number LSC 99714 to B&B Pharmacy. The Sterile Compounding Permit expired on August 26, 2015, and has not been renewed.

4. On or about March 8, 1995, the Board of Pharmacy issued Pharmacist License Number RPH 47817 to Suzy Michel Morkos (“Morkos”). The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on July 31, 2018, unless renewed. Morkos has been the Pharmacist-in-Charge of B&B Pharmacy since May 1, 2015.

JURISDICTION

5. This Accusation is brought before the Board of Pharmacy ("Board"), Department of Consumer Affairs, under the authority of the following laws. All section references are to the Business and Professions Code unless otherwise indicated.

6. Section 118, subdivision (b), of the Code provides that the suspension, expiration, surrender, or cancellation of a license shall not deprive the Board of jurisdiction to proceed with a disciplinary action during the period within which the license may be renewed, restored, reissued or reinstated.

7. Section 4011 of the Code provides that the Board shall administer and enforce both the Pharmacy Law, Business and Professions Code, § 4000, *et seq.*, and the Uniform Controlled Substances Act, Health and Safety Code, § 11000, *et seq.*

8. Section 4300.1 of the Business and Professions Code (“Code”) states:

The expiration, cancellation, forfeiture, or suspension of a board-issued license by operation of law or by order or decision of the board or a court of law, the placement of a license on a retired status, or the voluntary surrender of a license by a licensee shall not deprive the board of jurisdiction to commence or proceed with any investigation of, or action or disciplinary proceeding against, the licensee or to render a decision suspending or revoking the license.

STATUTORY PROVISIONS

9. Health and Safety Code section 111330 provides that, “Any drug or device is misbranded if its labeling is false or misleading in any particular.”

1 10. Health and Safety Code section 111440 provides that, "It is unlawful for any person to
2 manufacture, sell, deliver, hold, or offer for sale any drug or device that is misbranded."

3 11. Section 4059.5, subdivision (e), provides, in pertinent part, that:

4 (e) A dangerous drug or dangerous device shall not be transferred,
5 sold, or delivered to a person outside this state, whether foreign or
6 domestic, unless the transferor, seller, or deliverer does so in
compliance with the laws of this state and of the United States and
of the state or country to which the dangerous drugs or dangerous
devices are to be transferred, sold, or delivered. . . .

7 12. Section 4113, subdivision (c), provides that, "The pharmacist-in-charge shall be
8 responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining
9 to the practice of pharmacy."

10 13. Section 4169, subdivision (a)(3), of the Code provides that:

11 (a) A person or entity shall not do any of the following:

12 (3) Purchase, trade, sell, or transfer dangerous drugs that the
13 person knew or reasonably should have known were misbranded, as
defined in Section 111335 of the Health and Safety Code. . . .

14 14. Section 4301, subdivision (o), provides, that:

15 The board shall take action against any holder of a license who is
16 guilty of unprofessional conduct or whose license has been
issued by mistake. Unprofessional conduct shall include, but is not
limited to, any of the following:

17 (o) Violating or attempting to violate, directly or indirectly, or
18 assisting in or abetting the violation of or conspiring to violate any
provision or term of this chapter or of the applicable federal and
19 state laws and regulations governing pharmacy, including
regulations established by the board or by any other state or federal
regulatory agency.

20 15. Section 4307 provides, in relevant part, that:

21 (a) Any person who has been denied a license or whose license has
22 been revoked or is under suspension, or who has failed to renew his
or her license while it was under suspension, or who has been a
23 manager, administrator, owner, member, officer, director, associate,
partner, or any other person with management or control of any
24 partnership, corporation, trust, firm, or association whose
application for a license has been denied or revoked, is under
25 suspension or has been placed on probation, and while acting as the
manager, administrator, owner, member, officer, director, associate,
26 partner, or any other person with management or control had
knowledge of or knowingly participated in any conduct for which
27 the license was denied, revoked, suspended, or placed on probation,
shall be prohibited from serving as a manager, administrator,
28 owner, member, officer, director, associate, partner, or any other
person with management or control of a licensee as follows:

(1) Where a probationary license is issued or where an existing license is placed on probation, this prohibition shall remain in effect for a period not to exceed five years.

(2) Where the license is denied or revoked, the prohibition shall continue until the license is issued or reinstated.

(b) "Manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control of a license" as used in this section and Section 4308, may refer to a pharmacist or to any other person who serves in such capacity in or for a licensee. . . .

REGULATORY PROVISIONS

16. California Code of Regulations, title 16, section 1735.2, provides, in pertinent part, that:

(d) A drug product shall not be compounded until the pharmacy has first prepared a written master formula record that includes at least the following elements:

- (1) Active ingredients to be used.
- (2) Inactive ingredients to be used.
- (3) Process and/or procedure used to prepare the drug.
- (4) Quality reviews required at each step in preparation of the drug.
- (5) Post-compounding process or procedures required, if any.
- (6) Expiration dating requirements.

(h) Every compounded drug product shall be given an expiration date representing the date beyond which, in the professional judgment of the pharmacist performing or supervising the compounding, it should not be used. This "beyond use date" of the compounded drug product shall not exceed 180 days from preparation or the shortest expiration date of any component in the compounded drug product, unless a longer date is supported by stability studies of finished drugs or compounded drug products using the same components and packaging. Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist.

17. California Code of Regulations, title 16, section 1735.6, subdivision (b), provides that, "Any equipment used to compound drug products shall be stored, used, and maintained in accordance with manufacturers' specifications."

18. California Code of Regulations, title 16, section 1751.4, subdivision (d), provides that: Exterior workbench surfaces and other hard surfaces in the designated area, such as walls, floors, ceilings, shelves, tables, and stools, must be disinfected weekly and after any unanticipated event that could increase the risk of contamination.

19. California Code of Regulations, title 16, section 1751.7, subdivision (c), provides that: Batch-produced sterile injectable drug products compounded from one or more non-sterile ingredients shall be subject to documented

1 end product testing for sterility and pyrogens and shall be
2 quarantined until the end product testing confirms sterility and
3 acceptable levels of pyrogens.

4 OTHER PROVISIONS

5 20. Arizona Administrative Code section R4-23-607, subdivision (A)(1), provides that:

6 A. Permit. A person who is not a resident of Arizona shall not sell
7 or distribute any narcotic or other controlled substance,
8 prescription-only drug or device, nonprescription drug, precursor
9 chemical, or regulated chemical into Arizona without:

10 1. Processing a current Board-issued nonresident pharmacy
11 permit, nonresident manufacturer permit, nonresident full-service or
12 nonprescription drug wholesale permit, or nonresident
13 nonprescription drug permit;

14 COST RECOVERY

15 21. Section 125.3 of the Code provides, in pertinent part, that the Board may request the
16 administrative law judge to direct a licentiate found to have committed a violation or violations of
17 the licensing act to pay a sum not to exceed the reasonable costs of the investigation and
18 enforcement of the case, with failure of the licentiate to comply subjecting the license to not being
19 renewed or reinstated. If a case settles, recovery of investigation and enforcement costs may be
20 included in a stipulated settlement.

21 FIRST CAUSE FOR DISCIPLINE

22 (Failure to Clean)

23 Against Respondents B&B Pharmacy and Morkos

24 22. Respondents B&B Pharmacy and Morkos are subject to disciplinary action under
25 California Code of Regulations, title 16, section 1751.4, subdivision (d), in that all of the exterior
26 workbench surfaces and other hard surfaces in the designated sterile compounding area of the
27 pharmacy had not been disinfected on a weekly basis according to the pharmacy's own cleaning
28 logs.

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26 SECOND CAUSE FOR DISCIPLINE

27 (Misbranded Drugs)

28 Against Respondents B&B Pharmacy and Morkos

23. Respondents B&B Pharmacy and Morkos are subject to disciplinary action under Code section 4169, subdivision (a)(3), and Health and Safety Code sections 111330 and 111440 on the grounds that they manufactured, sold, delivered, held, and/or offered for sale misbranded drugs. The circumstances are as follows:

24. On or around October 27, 2015, Morkos provided pharmacy documents to a Board inspector that showed several lots of compounded drug products had been assigned improper beyond-use-dates ("BUDs"). For example, pharmacy documents showed that Lot No. 06022015@4 of Papaverine HCL Injection 33mg/mL Solution had been given a BUD of May 27, 2016, but one of its components, Lot No. C162544 of Chlorobutanol NF Anhydrous, had an earlier BUD of November 16, 2015. As another example, pharmacy documents showed that Lot No. 06302015@6 of Phentolamine 20mg/mL Injectable had been given a BUD of June 24, 2016, but one of its components, Lot No. 111930/K of Phentolamine Mesylate USP Powder had an earlier BUD of April 1, 2016. As yet another examine, pharmacy documents showed that Lot No. 05062015@12 of Alprostadil Alcohol Stock 500mcg/mL Solution had been given a BUD of April 30, 2016, but one of its components, Lot No. 98231/D of Alprostadil USP Powder had an earlier BUD of March 31, 2016.

THIRD CAUSE FOR DISCIPLINE

(Failure to Use Equipment In Accordance With Manufacturer's Specifications)

Against Respondents B&B Pharmacy and Morkos

25. Respondents B&B Pharmacy and Morkos are subject to disciplinary action under California Code of Regulations, title 16, section 1735.6, subdivision (b), on the grounds that they used certain equipment outside of the manufacturers' specifications to compound drugs. Specifically, Respondents used a Sharp convection microwave model R-390Ak/R-930AW and an Emerson 900W microwave oven model number MW8889SB during the compounding process to sterilize glassware or heat non-sterile drug preparations although both microwaves are only intended for household use.

FOURTH CAUSE FOR DISCIPLINE

(Failure to Prepare Master Formulas)

1 **Against Respondents B&B Pharmacy and Morkos**

2 26. Respondents B&B Pharmacy and Morkos are subject to disciplinary action under
3 California Code of Regulations, title 16, section 1735.2, subdivision (d), on the grounds that they
4 compounded drug products without complete written master formulas. The circumstances are as
5 follows:

6 27. On or around October 27, 2015, Morkos provided pharmacy documents to a Board
7 inspector that showed several lots of compounded drug products did not have complete written
8 master formulas. For example, there were no formula instructions or compounding steps to
9 prepare Lot No. 05062015@12 of Alprostadil Alcohol Stock 500mcg/mL Solution, Lot No.
10 06022015@4 of Papaverine HCL Injection 33mg/mL Solution, and Lot No. 08032015@2 of
11 Papaverine+PGE1+Phentolamine Injection 30mg:20mcg/mL Injectable. As another example, the
12 only formula instructions or compounding steps for Lot No. 06182013@16 of
13 Papaverine+PGE1+Phentolamine Injection 30mg:20mcg/mL Injectable was to “combine all
14 ingredients in sterile vial and seal.”

15 **FIFTH CAUSE FOR DISCIPLINE**

16 **(Failure to Assign Valid Beyond Use Dates)**

17 **Against Respondents B&B Pharmacy and Morkos**

18 28. Respondents B&B Pharmacy and Morkos are subject to disciplinary action under
19 California Code of Regulations, title 16, section 1735.2, subdivision (h), on the grounds that they
20 assigned improper BUDs to compounded drug products without the appropriate supporting
21 stability analyses. Complainant refers to and hereby incorporates the allegations contained within
22 paragraph 24, above, as though fully set forth herein.

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25 **SIXTH CAUSE FOR DISCIPLINE**

26 **(Failure to Have Valid Sterility Testing)**

27 **Against Respondents B&B Pharmacy and Morkos**

29. Respondents B&B Pharmacy and Morkos are subject to disciplinary action under California Code of Regulations, title 16, section 1751.7, subdivision (c), on the grounds that they failed to obtain end product testing for sterility and/or pyrogens on all compounded drug products. Specifically, Respondents failed to send a compliant sample size for sterility and pyrogens testing on Lot No. 06022015@4 of Papaverine HCL Injection 33mg/mL Solution, Lot No. 06302015@6 of Phentolamine 20mg/mL Injectable, and Lot No. 05062015@12 of Alprostadil Alcohol Stock 500mcg/mL Solution, and, therefore, had no documented end product testing on those lots.

SEVENTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct)

Against Respondents B&B Pharmacy and Morkos

30. Respondents B&B Pharmacy and Morkos are subject to disciplinary action under Code section 4301, subdivision (o), on the grounds that they violated, either directly or indirectly, or assisted in or abetted the violation of another state's laws and regulations governing pharmacies. The circumstances are as follows:

31. Between March 2012 and September 2015, Respondents prepared and shipped compounded drug products to an individual in Arizona on at least nine occasions. However, B&B Pharmacy did not have a nonresident permit under Arizona Administrative Code section R4-23-607, subdivision (A)(1), to sell or distribute drugs in Arizona.

EIGHTH CAUSE FOR DISCIPLINE

(Unlicensed Shipping to Arizona)

Against Respondents B&B Pharmacy and Morkos

32. Respondents B&B Pharmacy and Morkos are subject to disciplinary action under Code section 4059.5, subdivision (e), on the grounds that they transferred, sold, and/or delivered a dangerous drug to a person in Arizona without complying with all of the laws of the states of California and Arizona before doing so. Complainant refers to and hereby incorporates the allegations contained within paragraph 31, above, as though fully set forth herein.

OTHER MATTERS

33. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number

1 PHY 50799 issued to Respondent B&B Pharmacy, then Respondent B&B Pharmacy shall be
2 prohibited from serving as a manager, administrator, owner, member, officer, director, associate,
3 or partner of a licensee for five years if Pharmacy Permit Number PHY 50799 is placed on
4 probation or until Pharmacy Permit Number PHY 50799 is reinstated if it is revoked.

5 34. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number
6 PHY 50799 issued to Respondent B&B Pharmacy while Jane E. Hyun and/or Hyun Joon Ro,
7 Pharmacist License Number RPH 64426, have been officers and/or owners and had knowledge or
8 knowingly participated in any conduct for which the licensee was disciplined, then Jane E. Hyun
9 and/or Hyun Joon Ro shall be prohibited from serving as managers, administrators, owners,
10 members, officers, directors, associates, or partners of a licensee for five years if Pharmacy Permit
11 Number PHY 50799 is placed on probation or until Pharmacy Permit Number PHY 50799 is
12 reinstated if it is revoked.

13 **DISCIPLINARY CONSIDERATIONS**

14 35. To determine the degree of discipline, if any, to be imposed on Respondents,
15 Complainant alleges that, on or around August 13, 2012, Respondent B&B Pharmacy was issued
16 Citation No. CI 2011 50984 for violating Business and Professions Code section 4169, subdivision
17 (a)(4) [purchase, trade, sell, or transfer dangerous drugs or devices after or beyond use date on
18 label], in the amount of \$750, and California Code of Regulations, title 16, section 1751.7,
19 subdivision (a)(4) [written justification of the chosen expiration date for compounded sterile
20 injectable products], in the amount of \$500. Specifically, on or around January 6, 2012, during an
21 inspection of the pharmacy, it was discovered that B&B Pharmacy dispensed Amlodipine 5mg
22 beyond its labeled expiration date on multiple occasions between December 22, 2011, and January
23 6, 2012. It was also discovered that B&B Pharmacy did not have written justification for the
24 chosen expiration dates printed on the logged formula worksheets and stock bottle labels for
25 Apomorphine HCL 6mg/ml, dated November 2, 2011, and Baclofen Intrathecal 1mg/ml, dated
26 November 16, 2011, and that the chosen expiration dates did not correlate to the pharmacy's
27 master formulas.

36. To determine the degree of discipline, if any, to be imposed on Respondents, Complainant alleges that, on or around March 22, 2013, Respondent B&B Pharmacy was issued Citation No. CI 2011 51974 for violating Health and Safety Code section 11162.1, subdivision (a) [prescription forms for controlled substances; requirements], in the amount of \$5,000. Specifically, between March 26, 2012, and June 23, 2012, B&B Pharmacy dispensed the following prescriptions for controlled substances that were not printed in compliance with California security form requirements:

Dates	Drugs
6/23/12	Hydrocodone/acetaminophen (APAP) 5/500 #60
3/26/12	Carisoprodol 350mg #90
3/26/12	Alprazolam 5mg #60
3/26/12	Zolpidem 10mg #0
3/26/12	Hydrocodone (APAP) 10/325/ #60
3/26/12	Lorazepam 1mg #30
3/26/12	Hydrocodone (APAP) 10/325mg #60

37. To determine the degree of discipline, if any, to be imposed on Respondents, Complainant alleges that, on or around June 13, 2014, Respondent B&B Pharmacy was issued a letter of admonishment pursuant to Business and Professions Code section 4315 for failure to comply with the laws and regulations that govern the practice of pharmacy in California, including: (i) Business and Professions Code section 4315 and 4115, subdivision (f)(1) [ratio of pharmacists to pharmacy technicians]; (ii) California Code of Regulations, title 16, section 1751.7, subdivision (a)(4) [written justification on the chosen expiration date for compounded sterile injectable products]; (iii) California Code of Regulations, title 16, section 1751, subdivision (c) [batch produced sterile injectable drug products compounded from one or more non-sterile ingredients shall be subjected to documented end product testing and quarantined]; (iv) California Code of Regulations, title 16, section 1735.8, subdivision (c) [compounding quality assurance requires reports on integrity, potency, and quality]; (v) California Code of Regulations, title 16, sections 1735.6, subdivisions (b) and (c), 1735.5, subdivision (c), and 1735.3, subdivision (a)(7)

1 [compounding facilities and equipment, compounding policies and procedures, and records of
2 compounded drug products], (vi) Business and Professions Code section 4169, subdivision (a)(3),
3 in conjunction with California Code of Regulations, title 16, section 1735.2, subdivision (f)
4 [prohibited to purchase, trade, sell, or transfer dangerous drugs that a person knows or reasonably
5 should know are misbranded; pharmacist performing or supervising compounding is responsible
6 for the integrity, potency, quality, and labeled strength of a drug until it is dispensed]. Specifically,
7 on or around October 9, 2012, during an inspection of the pharmacy, multiple violations of
8 pharmacy law were observed under the aforementioned laws.

9 **PRAYER**

10 WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged,
11 and that following the hearing, the Board of Pharmacy issue a decision:

12 1. Revoking or suspending Original Permit Number PHY 50799, issued to Pacific
13 Healthcare Inc., dba B&B Pharmacy, Jane E. Hyun, Hyun Joon Ro;

14 2. Revoking or suspending Sterile Compounding Permit Number LSC 99714, issued to
15 Pacific Healthcare Inc., dba B&B Pharmacy, Jane E. Hyun, Hyun Joon Ro;

16 3. Revoking or suspending Pharmacist License Number RPH 47817, issued to Suzy
17 Michel Morkos;

18 4. Prohibiting Jane E. Hyun from serving as a manager, administrator, owner, member,
19 officer, director, associate, partner, or any other person with management or control of a licensee
20 for five years if Pharmacy Permit Number PHY 50799 is placed on probation or until Pharmacy
21 Permit Number PHY 50799 is reinstated if it is revoked.

22 5. Prohibiting Hyun Joon Ro, Pharmacist License Number RPH 64426, from serving as a
23 manager, administrator, owner, member, officer, director, associate, partner, or any other person
24 with management or control of a licensee for five years if Pharmacy Permit Number PHY 50799 is
25 placed on probation or until Pharmacy Permit Number PHY 50799 is reinstated if it is revoked.

26 6. Ordering B&B Pharmacy and Suzy Michel Morkos to pay the Board of Pharmacy the
27 reasonable costs of the investigation and enforcement of this case, pursuant to Business and
28 Professions Code section 125.3; and,

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7. Taking such other and further action as deemed necessary and proper.

DATED: 6/30/17 Virginia Herold

VIRGINIA HEROLD
Executive Officer
Board of Pharmacy
Department of Consumer Affairs
State of California
Complainant

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